

**Remarks**

The application has been reviewed in light of the Final Official Action mailed January 10, 2006. Claims 26 and 36 are amended. Claims 25-45 are pending in the Application. No new matter is introduced by the amendments. The amendments present a limitation incorporated in cancelled claim 1.

Applicants respectfully request that the Examiner enter the Amendments to claims 26 and 36. Claim 26 is amended to require "at least one axially extending groove is cut into an outer side of said screw body." Applicant believes that entry of this amendment is proper because this amendment corresponds to a dependent claim and does not alter scope of the independent claim 25, which has not been amended. Amended claim 36 is amended to require "at least three axially extending grooves cut into an outer side of said screw body." Applicant believes that entry of this amendment is proper because it incorporates a limitation previously presented to the Examiner, which clarifies the location of the grooves on the screw body, and would not require additional searching by the Examiner.

Applicants acknowledge that the Examiner considers claims 33-34 and 43-44 to contain allowable subject matter.

The Examiner Objected to claim 26 as being a substantial duplicate of claim 25. Applicants have amended claim 26 to require "at least one axially extending groove is cut into an outer side of said screw body." This limitation is not present in claim 25.

The Examiner has rejected claims 25-32 as unpatentable over Huebner (US 5,456,685) in view of Ross (US 5,470,334). Applicants respectfully requests that the Examiner reconsider this rejection in light of the fact that these references do not disclose a "screw head having a recess located therein" and a "tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion."

First, Applicants would like to note that the head of an interference screw corresponds to the proximal end of the screw. A head is a common term used with screws and is widely recognized as referring to a structure formed at the proximal end of a screw that receives a driving element. For instance the Application states that "the tool 40 as shown in FIG. 2 is slipped onto the interference screw 10 from the proximal end over the head portion 14." (par [0051]). Similarly Ross states that "[m]ost metallic bone screws include a threaded shank joined to an enlarged head having a transverse slot or hexagonal socket formed therein to engage, respectively, a similarly configured, single blade or hexagonal rotatable driver for turning the screw into a bone." (col. 1 l. 36-40). Ross goes on to state that "[a] drive recess 30 for receiving a rotatable driver is formed in body 12 to extend longitudinally from proximal end 14 in the direction of

distal end 16.” (col. 4 l. 50-52). Thus, Ross affirms the recognized convention that a driver approaches a screw from the proximal end of the screw and that this corresponds to the location of the head. As a result, Applicants respectfully submit that the limitation “said screw head having a recess located therein” requires a recess located in the screw head, which is at the proximal end of the screw.

Huebner does not anticipate claim 25 and its dependent claims because Huebner discloses a hexagonal socket 42 at the head of an interference screw, a front channel section 48 at the distal end of the screw, and a center channel section 46 that lies in-between. The Examiner notes that Huebner does not disclose “at least one extending groove running substantially the length of the screw body, a biodegradable material and the specifics of the drive tool.” (page 3). Applicants would also like to note that Huebner does not disclose “at least one axially extending groove” that receives a tool drive element and a “screw head having a recess located therein” that receives a tool protrusion. Huebner states that “[s]crew 12 is fitted onto a driver (not show) by inserting a hexagonal front end of the driver into socket 42 (FIG. 1).” (col. 3 l. 34-36). Fig. 1 shows that socket 42 is formed at the proximal end of the screw while front channel section 48 is formed at the distal end of the screw. Huebner does not disclose that there is also a recess located in the head of the screw that receives a tool protrusion. Based on the foregoing, Applicants respectfully submit that Huebner does not anticipate claims 25-33.

Ross does not anticipate the claim 25 and its dependent claims because Ross discloses a guide wire that is fed through a screw guide bore 50 and a tool guide bore 80, which help align the tool to the interference screw. Ross discloses that a drive recess 30 is formed at the head of the screw and extends axially towards the distal end 16 of the screw. (col. 4 l. 50-53). Ross states that the "length of the drive recess 30 from proximal end 14 to end wall 32 is approximately 48% to 95% the overall length of body 12 measured from proximal end 14 to distal end 16." (col. 5 l. 15-18). Ross discloses that the driver 60 is inserted into drive recess 30 for driving the screw and is centered with respect to the screw by an independent guide wire fed through the guide bore 50, and attached to the tool guide bore 80. Like Huebner, Ross does not anticipate the claimed invention because Ross does not disclose "at least one axially extending groove" that receives a tool drive element and a "screw head having a recess located therein" that receives a "tool having a protrusion."

Further, Ross fails to disclose a "tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion." Ross states that "[b]one screw 10 is inserted via guide bore 50 over a guide wire positioned in the femoral bone tunnel between the bone block positioned therein and the tunnel wall. Driver 60 is placed over the guide wire via guide bore 80 and is guided into mating engagement with drive recess 30 as shown in FIG. 5." (col. 7 l. 10-15). Thus, Ross discloses that the guide wire is a separate element that is not part of

the driver 60. The wire is fed through the screw and then attached to driver 60. Thus, Ross does not disclose "tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion."

Based on the foregoing, Applicants respectfully submit that Ross does not anticipate claims 25-33.

Further, Applicants respectfully submit that Hubner and Ross do not render claim 25 and its dependent claims obvious because there is no motivation or suggestion to modify or combine the references in accordance with these claims.

Hubner and Ross are directed to similar interference screws. Both disclose an interference screw with drive recess (or socket) at the proximal end (or head) of the screw, which receive and engage a drive element, and a screw guide bore (or front channel section) at the distal end of the screw, through which a guide wire is inserted. The cavities that form the drive recess and the screw guide bore communicate with each other such that the guide wire can pass through the entire length of the screw.

It is well settled that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). It is also well settled that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no sug-

gestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Huebner and Ross disclose a small diameter guide bore centered about the axis of the screw at the distal end of the screw. These references also disclose a larger diameter drive recess formed at the head of the screw, and centered about the axis of the screw, that corresponds to the shape of the driver. If the guide bore were moved from the distal end of the screw to the head of the screw, the drive recess would be displaced, i.e. the driver would no longer be able to drive the screw. As a result, one skilled in the art would not modify Huebner and Ross so that the guide bore is located at the head screw because such a modification would make those screws unsatisfactory for their intended purpose.

Even assuming that these references could be modified to include a recess at the head of an interference screw and a tool with a protrusion, one skilled in the art would have no motivation to make such a modification. Adding a recess to the head would merely duplicate the role of the guide bore at the distal end of the screw. Adding a protrusion to the tool for centering the tool would merely duplicate the function achieved by attaching an independent guide wire. Thus, one skilled in the art would not be motivated to add these limitations to these references' interference screws because these references already have different elements that achieve the objective of these limitations.

Still further, given the radial displacement of the drive recess formed in head of these interference screws, it is unclear how these interference screws could also incorporate an additional recess located in the head. In fact, such an embodiment is discouraged by Ross. As detailed below, Ross teaches that it is necessary for the outer wall of a biodegradable interface screw to be thick in order to assure the integrity of the interface screw. Having an interface screw head with a drive recess as disclosed by these references and an additional recess formed in the head for receiving a protrusion of a tool that centers the tool, would take away from the material dedicated to supporting the outer wall. As a result, one skilled in the art would not be motivated to make such a modification.

Since neither of these references disclose a "screw head having a recess located therein" and a "tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion," the combination of these references would not result in this limitation. Ross and Huebner disclose similar interference screws. Both incorporate a drive recess (or socket) at the proximal end of the screw and a screw guide bore (or front channel section) at the distal end of the screw. The notable difference between these references is the configuration of the drive recess that engages the driver. If Ross were applied to Huebner, the drive recess in Ross would be substituted for the socket in Huebner. If Huebner were applied to Ross, the socket in Huebner would be substituted for the drive recess in Ross. Simi-

larly, neither reference discloses a "tool having a protrusion" for centering the tool with the screw. Ross discloses threading an independent guide wire through the screw and attaching that wire to the tool to center the tool with the screw. The combination of these references would merely replicate this embodiment. However, the combination of these references would not yield a "screw head having a recess located therein" and a "tool having a protrusion corresponding to said recess in the screw head for centering said tool with respect to said screw body during insertion."

Based on the foregoing, Applicants respectfully submit that claims 25-32 are not rendered obvious by Huebner or Ross.

The Examiner has rejected claims 36-43 as unpatentable over Huebner (US 5,456,685) in view of Ross (US 5,470,334). Applicants respectfully submit that amended claim 36, and its dependent claims, are allowable over the cited references because these claims require "at least three axially extending grooves cut into an outer side of said screw body."

Applicants respectfully submit that both Huebner and Ross do not anticipate the claim 36 and its dependent claims because they both disclose interference screws with a drive recess (or socket) that is a hollow core in the screw and that receives a driver to drive the tool. The notable difference between these references is the configuration of the drive recess that engages the driver. The drivers are shaped to correspond to the



shape of the drive recesses. Neither discloses a biodegradable interference screw with "at least three axially extending grooves cut into an outer side of said screw body" or "tool including at least three drive elements for insertion into said at least three axially extending grooves." As a result, Applicants respectfully submit that neither Huebner nor Ross anticipate claim 36-42.

Further, Applicants respectfully submit that Huebner and Ross do not render claims 36-42 obvious because there is no motivation or suggestion to modify or combine the references in accordance with these claims.

It is well settled that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Both Huebner and Ross disclose interference screws that retain a hollow core that interfaces with a driver within the body of the screw. Neither reference suggests that a biodegradable interference screw could be modified to include "at least three axially extending grooves cut into an outer side of said screw body" or the driver could be modified to include "at least three drive elements for insertion into said at least three axially extending grooves." These limitations are directly contrary to the embodiments disclosed in Huebner and Ross. In fact Ross teaches away the use of multiprong drivers with biodegradable interference screws. Ross states that "bone screws made from bioabsorbable materials are susceptible to deformation and deflection when subjected

to forces required to drive the screw into relatively hard tissue, such as bone" (col. 2 l. 5-8). Ross goes on to state that "[m]ulti-pronged drive recesses designed for metallic screws generally cannot be employed successfully in bioabsorbable bone screws because the forces applied by compatible multi-pronged drivers to such drive recesses include outwardly directed force components that cause outward expansion, or 'mushrooming', in bioabsorbable bone screws." (col. 2 l. 45-51). In discussing the significance of that particular bone screw, Ross states that "[t]he relatively large minor diameter for the thread 18 in the proximal thread section 20 increases the quantity of screw material surrounding the drive recess 30 and, therefore, the strength of the bone screw in resisting shear and radial deformation when being rotated by a driver received in the drive recess." (col. 5 l. 29-34). Thus, Ross indicates that it is necessary for a biodegradable interference screw to have single drive recess formed as a hollow core. Ross also indicates that in order to preserve the integrity of a biodegradable interference screw, it is necessary to increase the quantity of screw material around the drive recess. As a result, one skilled in the art would not be motivated, and in fact discouraged, by Huebner or Ross to create a biodegradable interference screw with "at least three axially extending grooves cut into an outer side of said screw body" or "tool including at least three drive elements for insertion into said at least three axially extending grooves."

Further, since none of these references disclose "at least three axially extending grooves cut into an outer side of said screw body" or a "tool including at least three drive elements for insertion into said at least three axially extending grooves," the combination of these references would not result in this limitation. Ross and Huebner disclose similar interference screws that differ mainly in the shape of the drive recess and the corresponding shape of the drive element. If Ross were applied to Huebner, the drive recess in Ross would be substituted for the socket in Huebner. If Huebner were applied to Ross, the socket in Huebner would be substituted for the drive recess in Ross. However, the combination of these references would not yield "at least three axially extending grooves cut into an outer side of said screw body" or a "tool including at least three drive elements for insertion into said at least three axially extending grooves."

Based on the foregoing, Applicants respectfully submit that claims 36-42 are not obvious in view of Huebner or Ross.

For the foregoing reasons, Applicants respectfully submit that all pending claims are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,

March 7, 2006



Wesley W. Whitmyer, Jr., Registration No. 33,558  
Christopher H. Strate, Registration No. 57,376  
Attorneys for Applicants  
ST. ONGE STEWARD JOHNSTON & REENS LLC  
986 Bedford Street  
Stamford, CT 06905-5619  
203 324-6155